

REMARKS/ARGUMENTS

Claims 14-22, and 23-33 were pending. In the instant response, claims 14, 17, 20, 24, 32, 33, are amended and claim 34-42 are added. Support for the amendment to claims 14 and 24 can be found at least at page 3, lines 11-13. Claims 17, 20, 32, and 33 merely clarify the scope of the claimed invention. New claims 34-42 can be found in the specification in general and the claims as originally filed. Applicants submit that no new matter has been introduced by the instant amendment.

Issues under 35 U.S.C. §112, first paragraph

Claims 32-33 are rejected under 35 U.S.C. 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse. On page 3, lines 27-35, of the specification, it is disclosed that a combination of methods to reduce both the initial oxidative burst and subsequent inflammation associated damage could provide synergistic protection against reperfusion injury. Applicants submit that the inventors disclosed an exemplary application of the invention in section. In other words, the specification teaches preventing or ameliorating reperfusion injury by reducing the initial oxidative burst with a compound, for example, GLP-1, and reducing inflammation. Reducing inflammation is an art recognized step, such as by administering an anti-inflammatory. Accordingly, one of ordinary skill in the art reading this passage in the context of the entire specification would understand that the inventors had possession of the claimed invention, reducing the oxidative burst by the methods of the instant invention and combining it with reducing inflammation, at the time of filing.

Claims 14-33 are similarly rejected under 35 U.S.C. 112, first paragraph. The Patent Office alleges that the Applicants have not taught a method of preventing a decrease in normal function of ischemic and reperfused tissue comprising administering a compound that binds to

GLP-1 receptor or any exendin peptide, or a compound that is an exendin derivative, or a GLP-1 analog.

Applicants respectfully submit that they have taught a method of preventing a decrease in function of tissue that has undergone an ischemic-reperfusion event. The scope of the claimed invention necessitates that the tissue undergo a reperfusion event. As disclosed in the specification, Applicants submit that the claimed invention may prevent a decrease in the function of reperfused tissue. It is the Applicants' belief that the burden is on the Patent Office to explain why it doubts the truth or accuracy of this statement and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *Marzocchi*, 439, F.2d 220, 224 (CCPA 1971). Applicants also note that the scope of the term "ameliorate" includes slight improvements to full improvements (or prevention).

Applicants have amended the claims to be directed to compounds that activate a receptor for GLP-1. Such compounds, *e.g.*, GLP-1, GLP-1 analogs and exendins, are recognizable to one of ordinary skill in the art and a representative number of compounds are also set forth in the specification, page 11, line 31, to page 16, line 17. Thus, the skilled artisan would be able to envision the scope of the claimed invention. It should be remembered that the claimed invention is directed to the prevention and amelioration of decreased function of reperfused tissue by administering a compound that activates a receptor for GLP-1. Applicants have exemplified a representative number of such compounds. Applicants do not seek to claim compounds that activate a receptor for GLP-1. To require that Applicants set forth every conceivable compound that activates a receptor for GLP-1 in order to obtain the protection to which they are entitled would place an onerous burden on the Applicants or allow third parties to easily avoid infringing the claims.

In light of the arguments provided above, Applicants respectfully request reconsideration and withdrawal of the rejection.

Issues under 35 U.S.C. §112, second paragraph

Claims 14 and 24 are rejected because the Patent Office alleges that “a decrease in a function of a tissue” is unclear. Applicants have amended claims 14 and 24 to more particularly describe the claimed invention.

Claims 16 and 26 are rejected because the Patent Office alleges that the Markush group contains a broad term “combinations thereof” and narrower terms. Applicants respectfully submit that the use of the broad and narrower terms in the present context clearly sets forth the metes and bounds of the patent protection desired. Applicants submit that the Markush group includes the narrower terms in combination. Applicants, instead of setting forth each and every combination, have used a shorthand phrase to encompass this group.

Claim 17, 20, and 24 is rejected because the Patent Office alleges that “treatment” “infusion” and “compound” are unclear. The claims, as amended, obviate these rejections.

Claim 32 is rejected because the Patent Office alleges that “reducing an inflammatory response” is a process and not a step. Applicants have amended claim 32.

Applicants respectfully request reconsideration and withdrawal of all outstanding rejections to the claims.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and request that a timely Notice of Allowance be issued in this case. The Examiner is encouraged to call the undersigned attorney to discuss any issues related to the prosecution of the instant application.

Applicants believe that no fee is necessitated by the present paper. However, in the event any fees are due or any amount is to be credited, Applicants authorize the Commissioner of Patents to debit or credit Deposit Account No. 010535.

Respectfully submitted,



Mi K. Kim
Reg. No. 44,830

AMYLIN PHARMACEUTICALS, INC.
9360 Towne Centre Drive
San Diego, CA 92121
Phone: (858) 552-2200
Facsimile: (858) 552-1936